Calendar No. 177

109TH CONGRESS, *1st Session* | SENATE | REPORT 109–110

TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO PROVIDE FOR THE REGULATION OF ALL CONTACT LENSES AS MEDICAL DEVICES, AND FOR OTHER PURPOSES

JULY 27, 2005.—Ordered to be printed

Mr. ENZI, from the Committee on Health, Education, Labor, and Pensions, submitted the following

REPORT

[To accompany S. 172]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 172) to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

CONTENTS

I. PURPOSE AND SUMMARY OF THE BILL

The purpose of S.172 is to provide for the regulation of all contact lenses as medical devices. S. 172 amends Section 520 of the Federal Food, Drug, and Cosmetic Act (FFDCA) by adding a subsection (n) that deems all contact lenses to be medical devices under Section 201(h) of the FFDCA.

II. Background and Need for Legislation

"Plano" contact lenses are zero powered, non-corrective contact lenses that are used to change the appearance of the normal eye in a decorative fashion. Most contact lenses currently marketed in the United States, including certain plano and decorative contact lenses, have been cleared as medical devices pursuant to premarket notifications under Section 510(k) of the FFDCA by the Food and Drug Administration (FDA). The FDA has asserted medical device jurisdiction over most corrective and noncorrective contact lenses currently marketed in the United States, including certain plano and decorative contact lenses, so as to require approval pursuant to premarket approval applications under Section 515 of the FFDCA or clearance pursuant to premarket notifications for dispensing pursuant to the lawful prescriptions of eye care professionals.

However, some non-corrective, decorative contact lenses have not been approved by FDA and are sold without a prescription. The FDA regulates these non-corrective contact lenses under its cosmetic authority in Chapter VI of the FFDCA. These contact lenses present a public health threat.

One such example involved a teenage girl from Cleveland who bought colored contact lenses from a video rental store for the purpose of matching her eyes with her dress. The lenses were sold without fitting or instruction. Shortly after wearing the colored contact lenses, she was admitted to a Cleveland hospital where her left eye become so badly infected the doctor feared that she might not only lose her sight, but she could actually lose her eye. She was in the intensive care unit for 4 days.

The problem is national in scale. Contact lens insertion without appropriate supervision and fitting has been linked to ocular ulcers, as well as temporary and permanent vision problems. In Wyoming, Dr. Roger Jordan of Gillette reported a personal experience with a teenager who came in to see him with vision problems that resulted from an unlicensed person giving her plano lens that she put over her corrective lenses.

III. Legislative History and Committee Action

On January 26, 2005, Senator DeWine, for himself and Senator Kennedy, introduced S. 172, to provide for the regulation of all contact lenses as medical devices. On March 9, 2005, the committee held an executive session to consider S. 172. After accepting an amendment in the nature of a substitute, the committee approved S. 172, as amended, by unanimous voice vote.

IV. Explanation of Bill and Committee Views

There is an overwhelming public health consensus that it is necessary for these products to be regulated as medical devices. However, because the companies marketing these plano lenses, mostly importers, have avoided making health claims for their products, the FDA regulates them as cosmetics, not medical devices. The committee's action is not intended to create law for or against FDA's regulatory approach in this case. S. 172 achieves this result by including a rule of construction providing that the bill's sub-

stantive provision shall not be construed as having any legal effect on any other article regulated under the FFDCA.

S. 172 automatically deems all contact lenses to be medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA") to ensure that all contact lenses are properly manufactured and used only with the appropriate involvement of a qualified eye care professional while avoiding any complex legal or policy issues. In the highly regulated arena of products governed by the FFDCA, such product-focused legislation is not unusual. Thus, for example, in 1990, Congress enacted specific medical device provisions relating to daily wear soft and nonhydrophilic plastic contact lenses. S. 172 achieves a similar outcome by addressing unanticipated developments in the marketplace with respect to one particular form of contact lens.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, April 15, 2005.

Hon. MICHAEL B. ENZI,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 172, a bill to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

ELIZABETH M. ROBINSON
(For Douglas Holtz-Eakin, Director).

Enclosure

S. 172—A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes

S. 172 would amend the Federal Food, Drug, and Cosmetic Act (FDCA) to require that the Food and Drug Administration (FDA) regulate all contact lens products as medical devices.

FDA currently regulates all contact lenses as medical devices except for decorative, noncorrective lenses, which FDA currently regulates as cosmetics. S. 172 would deem all contact lenses to be medical devices under the FDCA. Based on information from FDA, CBO expects that the additional cost for FDA to regulate decorative contact lenses as medical devices beyond its cost to regulate such products as cosmetics under current law would be negligible. Assuming the availability of appropriated amounts, CBO estimates that implementing S. 172 would cost FDA less than $500,000 annually.

CBO expects that changing the regulatory classification of decorative, non-corrective lenses to medical devices would likely lead to FDA requiring that those products be available only by prescription. (For decorative, non-corrective lenses, a prescription-only label would require the oversight of an eye care professional to ensure

proper fitting and use.) In response, we anticipate that the Federal Trade Commission (FTC) would expand its regulation of prescription contact lenses to include decorative non-corrective contact lenses. Based on information provided by the FTC, CBO estimates that implementing S. 172 would not have a significant impact on spending subject to appropriation for that agency.

The legislation would not affect direct spending. There would be potential for higher revenues through penalties imposed by FDA and the FTC for violations of Federal laws under their respective jurisdictions related to contact lenses. Such collections of civil penalties are recorded in the budget as revenues. However, based on information provided by the agencies, CBO expects that revenues from any penalties collected as a result of enacting S. 172 would be negligible.

S. 172 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform act (UMRA) and would impose no costs on state, local, or tribal governments. However, the bill would impose private-sector mandates on sellers, prescribers and manufacturers of decorative non-corrective lenses by making them subject to more stringent federal regulatory requirements for medical devices. CBO estimates that the direct costs of the mandates in the bill would not exceed the threshold established in UMRA ($123 million in 2005, adjusted annually for inflation) in any of the first 5 years the mandate would be effective.

A mandate would be imposed on sellers and prescribers because, as medical devices, such contact lenses would more likely require prescription verification. CBO expects that prescribers of decorative, non-corrective lenses would have to provide the patient with a copy of the prescription and to verify the prescription to third-party manufacturers. Since eye care professionals need only return the call of a third-party manufacturer if the prescription the manufacturer has is wrong, CBO estimates that the costs to these entities would be insignificant.

S. 172 also would impose a private-sector mandate on manufacturers. Based on information from industry and government sources, CBO estimates that most major manufacturers already produce decorative, non-corrective contact lenses under standards that would meet the tighter FDA requirements. For the remaining manufacturers, CBO estimates that the cost of upgrading production processes and obtaining FDA approval would not be significant.

The CBO staff contacts for this estimate are Julia Christensen and Melissa Zimmerman, for the Federal budget impact, Leo Lex, for the State and local impact and Meena Fernandes, for the private-sector impact. This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

VI. Application of Law to the Legislative Branch

S. 172 amends Section 520 of the FFDCA to deem all contact lenses to be medical devices. As such, it has no application to the legislative branch.

VII. Regulatory Impact Statement

The legislation amends Section 520 of the FFDCA to deem all contact lenses to be medical devices. Decorative lenses now regulated as cosmetics would be regulated as medical devices, requiring that they be available only by prescription and the oversight of a qualified eye care professional to ensure proper fitting and use. Accordingly, CBO anticipate S. 172 will result in a slight increase in cost to the public. CBO anticipates that the Federal Trade Commission will expand its regulation of prescription contact lenses to include all decorative, non-corrective contact lenses. CBO estimates that implementing S. 172 would not have a significant impact on spending subject to appropriation for that agency. Pursuant to the requirements of paragraph 11(b) of Rule XXVI of the Standing Rules of the Senate, the committee has determined that the bill will not have a significant regulatory impact.

VIII. Section-by-Section Analysis

Sec. 1. Findings

Sec. 2. Regulation of certain articles as medical devices

Section 2 amends Section 520 of the FFDCA by adding a new subsection (n). Paragraph (1) of the new section 520(n) deems all contact lenses to be medical devices.

Paragraph (2) of the new section 520(n) makes clear that paragraph (1) does not have any legal effect on any article other than a contact lens.

IX. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

General Rule

Sec. 520. (a) Any requirement authorized by or under section 501, 502, 510, or 519 applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 513, 514, or 515 or under subsection (g) of this section, and any requirement established by or under section 501, 502, 510, or 519 which is inconsistent with a requirement imposed on such device under section 514 or 515 or under subsection (g) of this section shall not apply to such device.

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(m)(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States.

(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 514 and 515 for a device for which the Secretary finds that—

(A) * * *

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Regulation of contact lens as devices

(n)(1) All contact lenses shall be deemed to be devices under section 201(h).

(2) Paragraph (1) shall not be construed as having any legal effect on any article that is not subject to such paragraph.

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